On Call® Advanced

Blood Glucose Test Strip Package Insert

REF G134-101	English

PRINCIPLE AND INTENDED USE

The *On Call ® Advanced* Test Strips are thin strips with a chemical reagent system which work with the *On Call ® Advanced* Blood Glucose Meter to measure the glucose concentration in whole blood. Blood is applied to the end tip of the test strip, then automatically absorbed into the reaction cell where the reaction takes place. A transient electrical current is formed during the reaction and the blood glucose concentration is calculated based on the electrical current detected by the meter, then the result is shown on the meter display. The meters are calibrated to display plasma equivalent results.

For *in vitro* diagnostic use. Test strips are only to be used outside the body for testing purposes. *On Call ® Advanced* Test Strips are used by people with diabetes at home and by healthcare professionals for the quantitative measurement of glucose in capillary whole blood from the finger, forearm, and palm. It is also used as an aid in monitoring the effectiveness of diabetes control programs. Professionals may also test neonatal, venous and arterial blood samples.

COMPOSITION

Each test strip contains the following reactive chemicals: Glucose dehydrogenase < 25 IU, Mediator < 300 ug, Buffer, Non-reactive Ingredient.
Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Test strips should be stored tightly capped in their protective vial to keep them in good working condition.
- Store test strips in a cool, dry place at room temperature, 2-30°C (36-86°F). Store them away from heat and direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips at room temperature. This is to ensure accurate results.
- Do not store the test strips outside their protective vial. Test strips must be stored in the original vial with the cap tightly closed.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners that contain bleach.
- Do not transfer the test strips to a new vial or any other container.
- Replace the vial cap immediately after removing a test strip.
- Use the test strip immediately after removing it from the vial.
- Do not use your test strips past the unopened expiration date printed on the vial. Using test strips past the expiration date may produce incorrect test results.
  Note: All expiration dates are printed in Year-Month format. 2010-01 means January, 2010.
- A new vial of test strips may be used for 6 months after first being opened. The opened vial expiration date is 6 months after the date the vial was first opened. Write the opened vial expiration date on the vial label after opening.

PRECAUTIONS

- For *in vitro* diagnostic use. The test strips are to be used only outside the body for testing purposes.
- Do not use test strips after the expiration date shown on the vial. Expired test strips may give incorrect blood glucose readings.
- Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.
- Only apply the sample to the tip of the test strip. Do not apply blood or control solution to the top of the test strip. This may result in an inaccurate reading.
- Check the code chip before running a blood glucose test. Make sure to use the code chip that is included with that vial of strips. Insert the code chip into the code chip slot. The code chip slot is located on the right side of the meter.
- Discard the vial and any unused test strips 6 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This damage can cause incorrect readings.
- Keep the test strip vial away from children and animals.
- Consult your physician or healthcare professional before making any changes in your treatment plan based on your blood glucose test results.

MATERIALS PROVIDED

- Test Strips
- Code Chip
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Sterile Lancets
- Lancing Device
- Control Solution

INSTRUCTIONS FOR USE

See your User's Manual for complete instructions for blood sample collection before use.

1. Open the cap of the test strip vial only to remove a test strip for testing. Replace the cap immediately to protect the remaining test strips from moisture in the air.
2. Run the blood glucose test following the instructions contained in your user's manual.
3. The blood glucose test result will be shown on the meter display window. This result should fall within the target range recommended by your healthcare professional. If your blood glucose test results are higher or lower, ask your healthcare professional what to do. Always consult your healthcare professional before making any changes to your treatment plan.

IMPORTANT: *On Call ® Advanced* Blood Glucose Monitoring System allows alternative site testing for forearm and palm testing in additional to fingertip testing. There are important differences between forearm, palm and fingertip samples that you should know. Important information about forearm and palm glucose testing:

- When blood levels are changing rapidly such as after a meal, insulin dose or exercise, blood from the fingertips may show these changes more rapidly than blood from other areas.
- Fingertips should be used if testing is within 2 hours of a meal, insulin dose or exercise and any time you feel glucose levels are changing rapidly.
- You should test with the fingertips anytime there is a concern for hypoglycemia or you suffer from hypoglycemia unawareness.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a healthcare professional. Together you can set your own range of expected blood glucose values, arrange your testing times, and discuss the meaning of your blood glucose results.
Expected blood glucose levels for people without diabetes:[1]

Time	Range (mg/dL)	Range (mmol/L)
Fasting and Before Meals	70 – 100	3.9 – 5.6
2 Hours After Meal	Less than 140	Less than 7.8

CHECKING THE SYSTEM

Your blood glucose meter must be handled carefully. See your user's manual for detailed instructions for meter care. The quality control test should be used to check that the meter and test strips are working together properly. Follow the test procedure in your user's manual to run a quality control test. Two ranges CTRL 1 and CTRL 2 are shown on the test strip vial label. Control Solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 test. Contact your dealer for information on purchasing control solution.

For confirmation of results, Control Solution 1 tests should fall within the CTRL 1 range, and Control Solution 2 tests should fall within the CTRL 2 range. When testing with Control Solution 1, make sure you are matching the results to the CTRL 1 range on the vial label.

CAUTION: If your quality control test result falls outside the control range shown on the test strip vial, DO NOT use the system to test your blood, as the system may not be working properly. If you cannot correct the problem, contact your dealer for help.

LIMITATIONS

WARNING: To avoid false readings, do not use *On Call ® Advanced* Blood Glucose Monitoring System if you are taking drugs that break down to maltose or galactose. These drugs can cause inaccurate blood sugar test results due to the increase in maltose or galactose presence in the blood.

The following represent some drugs that may lead to false readings:

- Peritoneal dialysis solutions containing icodextrin (e.g., Extraneal, Icodial)
- Certain types of intravenous immunoglobulin therapies (e.g., Octagam® 5%)
- Intravenous solutions containing maltose as a means for patient hydration

NOTE: To determine if a drug breaks down to maltose or galactose, please consult the drug package insert. The list above is not meant to be an all inclusive list and may be missing other drugs.

- Don't use *On Call ® Advanced* Blood Glucose Monitoring System during a xylose absorption test.
- Blood glucose level readings may be overestimated if concentration for galactose levels > 10 mg/dL, maltose levels > 13 mg/dL in the blood, or lactose levels > 5 mg/dL.
- The meter, test strips and other components have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- Do not use the meter in any manner not specified by the manufacturer. Otherwise, the protection provided by the meter may be impaired.
- The *On Call ® Advanced* Test Strips are for testing fresh capillary, venous, neonatal or arterial whole blood. Do not use with serum or plasma samples.
- The *On Call ® Advanced* Blood Glucose Monitoring System is indicated for professional use and over the counter sale. Professionals may use the test strips to test capillary, venous, neonatal and arterial blood samples; user is limited to capillary whole blood testing.
- Blood glucose measurement with venous or arterial blood must be performed within 15 minutes of sample collection.
- Anticoagulant preservatives such as heparin or EDTA are recommended for best results in using venous or arterial blood. Use of anticoagulants such as iodoacetate, sodium citrate, or those containing fluoride is not advised.
- Very high (above 70%) and very low (below 20%) hematocrit can cause false results. Talk to your healthcare professional to find out your hematocrit level.
- Abnormally high levels of Vitamin C (ascorbic acid), acetaminophen, uric acid or other reducing substances will produce falsely high blood glucose measurements.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 0.6-33.3 mmol/L (10 to 600 mg/dL).
- Fatty substances (Triglycerides up to 3,000 mg/dL or Cholesterol up to 500 mg/dL) have no major effect on blood glucose test results.
- The *On Call ® Advanced* Blood Glucose Monitoring System has been tested and shown to work properly up to 10,000 ft (3,048 meters).
- Severely ill persons should not run the glucose test with the *On Call ® Advanced* Blood Glucose Monitoring System.
- Blood samples from patients in shock, or with severe dehydration or from patients in a hyperosmolar state (with or without ketosis) have not been tested and are not recommended for testing with *On Call ® Advanced* Blood Glucose Monitoring System.
- Dispose of blood samples and materials carefully. Treat all blood samples as if they are infectious materials. Follow proper precautions and obey all local regulations when disposing of blood samples and materials.

PERFORMANCE CHARACTERISTICS

Reproducibility and Precision

Ten replicate assays were each run on ten *On Call ® Advanced* Blood Glucose Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results concluded the following reproducibility and precision estimates.

MEAN	47.6 mg/dL	91.1 mg/dL	140.2 mg/dL	219.5 mg/dL	360.3 mg/dL
Standard Deviation (mg/dL) or Coefficient of Variation (CV)	1.12 mg/dL (SD)	2.4%	2.9%	2.9%	3.2%

Intermediate Precision

Ten replicate assays drawn from 3 strip lots were run on ten *On Call ® Advanced* Blood Glucose Meters each day for a total of 10 days. Control solutions at three concentration levels were used in the testing. The results concluded the following intermediate precision estimates.

#	MEAN	Standard Deviation (mg/dL) or Coefficient of Variation (CV)
Strip Lot 1	44.3 mg/dL	0.8 mg/dL (SD)
	125.3 mg/dL	1.8%
	377.8 mg/dL	2.0%
Strip Lot 2	45.5 mg/dL	1.0 mg/dL (SD)
	125.7 mg/dL	1.9%
	373.8 mg/dL	1.7%
Strip Lot 3	43.5 mg/dL	1.2 mg/dL (SD)
	126.0 mg/dL	2.2%
	373.7 mg/dL	2.2%

System Accuracy

The capillary blood glucose measurements from 115 participants were taken by a trained technician using the *On Call ® Advanced* Blood Glucose Meter (y). Capillary blood samples were obtained from fingertip, palm and forearm sampling sites for the *On Call ® Advanced* Blood Glucose Meter testing. Fingertip samples from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared in the table below.

Linear Regression Results: *On Call ® Advanced* (y) vs. YSI Reference (x)

Sample Site	Slope	Intercept	R	N
Fingertip	0.9924	2.4070	0.9961	230
Palm	0.9826	3.0104	0.9940	210
Forearm	0.9663	5.4649	0.9889	210

Fingertip samples were used for YSI reference measurement.
The sample range was 21.6 to 558 mg/dL for *On Call ® Advanced* Blood Glucose Meter testing with blood sampled from fingertip sites. The sample range was 79.2 to 438 mg/dL for *On Call ® Advanced* Blood Glucose Meter testing with blood sampled from palm and forearm sites.

Fingertip Site: System accuracy results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
12/12 (100%)	12/12 (100%)	12/12 (100%)

Fingertip Site: System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
155/218 (71.1%)	211/218 (96.8%)	217/218 (99.5%)	218/218 (100%)

Palm Site: System accuracy results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
N/A	N/A	N/A

Palm Site: System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
148/210 (70.5%)	196/210 (93.3%)	207/210 (98.6%)	210/210 (100%)

Forearm Site: System accuracy results for glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
N/A	N/A	N/A

Forearm Site: System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
128/210 (61.0%)	191/210 (91%)	203/210 (96.7%)	210/210 (100%)

Consumer Study

A consumer study was performed by testing three test strip lots with capillary blood sample. Participants and a trained technician both used the *On Call ® Advanced* Blood Glucose Monitoring System. This study showed that the patient can run the test as well as a trained technician.

On Call ® Advanced tests: Linear regression of Participant (y) versus YSI Reference value, and Linear regression of Technician (x) versus YSI Reference value

Strip Lot	Test By	Slope	y-Intercept	R	N
Strip Lot 1	Layperson	1.0218	-0.4215	0.9936	104
Strip Lot 1	Technician	0.9957	3.0506	0.9954	104
Strip Lot 2	Layperson	0.9944	2.2157	0.9931	208
Strip Lot 2	Technician	1.0031	0.9906	0.9947	208
Strip Lot 3	Layperson	0.9795	2.3250	0.9949	104
Strip Lot 3	Technician	0.9727	4.0552	0.9949	104

Venous Study

The venous blood glucose measurements from 106 participants were taken by a trained technician using the *On Call ® Advanced* Blood Glucose Meter (y). The venous blood sample from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared in the table below.

Linear Regression Results: *On Call ® Advanced* (y) vs. YSI Reference (x)

Blood Sample	Slope	Intercept	R	N
Venous	0.9900	-2.189	0.9925	200

Neonatal Study

The neonatal blood glucose measurements from 106 participants were taken by a trained technician using the *On Call ® Advanced* Blood Glucose Meter (y). The neonatal blood sample from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared in the table below.

Linear Regression Results: *On Call ® Advanced* (y) vs. YSI Reference (x)

Blood Sample	Slope	Intercept	R	N
Neonatal	0.9570	1.4342	0.9860	212

Arterial Study

The arterial blood glucose measurements from 100 participants were taken by a trained technician using the *On Call ® Advanced* Blood Glucose Meter (y). The arterial blood sample from the same subjects were also analyzed with YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared in the table below.

Linear Regression Results: *On Call ® Advanced* (y) vs. YSI Reference (x)

Blood Sample	Slope	Intercept	R	N
Arterial	1.0156	-5.0976	0.9908	200

For complete instructions, please refer to the *On Call ® Advanced* user's manual. For additional questions or issues with this product, please contact your dealer for help.

REFERENCES

1. ADA Clinical Practice Recommendations, 2003.

INDEX OF SYMBOLS

	Consult instructions for use		Use by	CODE	Code Number
IVD	For *in vitro* diagnostic use only	LOT	Lot Number	CTRL	Control Range
2°C 30°C	Store between 2-30°C		Manufacturer	**REF**	Catalog #
Σ	Contains sufficient for <n> tests	EC REP	Authorized Representative in the European Community		

ACON®

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Effective Date: 2010-xx-xx